

EXHIBIT B

ABBOTT LABORATORIES
RESEARCH DEPARTMENT

PROJECT HCV combo Assay
EXP. OR CODE NO. Ab, Ag Blended up and conj

This is the first demonstration of a combination antibody/Ag test for HCV.

cont. on pge #10

Blended Up and Blended conjugate
Up: HC31 (DF=3 Coating conc: 200ug/ml) + C11-14 (0.09% 0.4um)
Conjugate: C11-10 (100ng/ml 1:16) + 6A52B (1/5 dilution in HIV combo CD)
Washes: HIV ag transfer wash Dev lot 5/ final wash : HCV Ag prep.
SDB: 6A52Q
Up diluent: 18498 HCV Ab assay up diluent
S/A configuration: HCV

1023 V COMBO ASSAY 6 A N/A 08/21/00 21:29:16 L JUNG

Samples	SubA	SubB	Combo Assay Mean counts	PIN	Ab Assay Mean Counts 08/28/00	PIN	Ag Assay Mean counts 08/24/00	PIN
PC (Ab)	1502	1023	1712.5	2.17	33952	8.64		
NC (Ab)	808	852	780		3930.17		79	
	755	745	719	0.91	4818.75	1.23		
98800	719	1083	1110	1.41	36800.87	9.36		
Panel A	1187	8035	8410	11.91	147307.5	37.48		
E2 1/20 dill	9785	8237	8104.5	10.28				
Promed 9892161	7972	3639	3094.5	3.92				
PC JV 016828	2550	5280	5258.5	6.68				
PC JV017220	5227	889	870.5	1.10				
Sero-Tec panel #3	842	1773	1863.5	2.36	1427	0.36	4409.83	55.82
4	1954	2463	2507.5		2059.5	0.52	6980.5	88.36
6	2552	3507	3556.5		1704.5	0.43	881.5	10.81
6	3806	3120	3001		1716.5	0.44	2645	33.88
7	2882	2280	2172.5		1607.5	0.38	4708.5	59.58
8	2055	3707	3707		1871.5	0.43	5071	64.12
8					1665	0.43	4258	53.03
						0.42	2853	35.11
							4829	61.13

1277

21511

As the first Blend up and conj. results are encouraging. Dilute conj more for next run.

SIGNATURE [Signature]

DATE

WITNESSED BY [Signature]

DATE

PROJECT HCV combo Assay

EXP. OR CODE NO. Cont. from page # 8

DESCRIPTION OF PANEL MEMBERS -

NC - negative control - pooled plasma individually screened as negative for HCV antibodies by a commercialized assay- Code: 6A52E. Prism HCV Ab Assay Negative Calibrator.
PC - positive control - pooled anti-HCV positive plasma diluted in negative control . Code: 6A52F. Prism HCV Ab Assay Positive Calibrator.

99800 - Plasma(human) Recalcified Negative Bulk.

Panel A - an anti-HCV positive plasma that has been diluted in negative control to provide a mid range sample to cutoff in the PRISM antibody assay.

E2 1/20 - an anti-HCV positive sample that has been diluted in negative control - the E2 antibody panel was utilized to titrate the potency of HCV E2 antigen coated microparticles

Promed 9992161 - an antibody positive sample obtained from ProMeDx (Plainville, MA)

PC JV 16929 - Sero-Tec HCV RNA positive human plasma .
PC P JV17220 - Sero-Tec HCV RNA positive human plasma .

SeraTec Panel members 3-9 - serial bleeds obtained from a plasma donor identified at SeraTec as being anti-HCV negative and HCV antigen positive.

A panel of specimens previously characterized as having antibodies to HCV or being negative for antibodies to HCV but positive for HCV RNA and HCV antigens were tested in a preliminary HCV combination antibody antigen test.

Reagents utilized in combo test

Microparticles specific for HCV antigen detection (up's coated with C11-14 as described on RB: 67093 page 100) and microparticles specific for HCV antibody detection (up's coated with HCV recombinant protein HC 31 as described on RB: 68160page 2) were blended to produce a solid phase that would allow simultaneous detection of HCV antibodies and HCV antigens in a single reaction well. (The blended microparticles contained 0.19% solids, representing a mixture of 0.09% up's coated with C11-14 and 0.1% coated with HC31). The conjugates were also a mixture of two separate acridinium labeled proteins. Acridinium labeled C11-10 was utilized for HCV antigen detection (recognizing HCV antigens captured on the C11-14 microparticles) and an acridinium labeled monoclonal antibodies against biotin -labeled goat anti-human IgG (presented as a pre-complex - see RB: 52226m301) was utilized to detect human anti-HCV IgG bound to the HC-31 coated microparticles.

Results

The panel described above was run on 3 different PRISM-based assays. One of the assays detected HCV antibodies, a second test detected HCV antigens and a third test (the combo assay) detected both HCV antibodies and HCV antigens. Samples have a positive to negative ratio (P/N) ratio of 3.0 or greater were considered positive. The data presented in the table on RB68160page 8 indicate that the combo assay allows detection both of antibody positive samples (e.g. panel E2 1/20, ProMed 9992161, PC JV 016929 and PC JV 17220) and HCV antigen positive samples (Sera Tec panel members 5-9). Thus, this single combo assay performed in a single reaction well detects most of the samples that were positive in two separately performed assays, the HCV antibody test and the HCV antigen test. This is the first demonstration of a combo HCV antibody / HCV antigen test at Abbott Laboratories, and is the first example of the HCV antibody /antigen combo test ideas presented in Redbook 61,959: pages 1-8. Other iterations of the HCV combo test will be presented over the next several weeks/months.

S Expt.

Willy
For
more description of
the

SIGNATURE Willy DATE _____

WITNESSED BY Cathy Koon DATE _____

PROJECT _____

EXP. OR CODE NO. Cont. from page # 18

BOSTON BIOMEDICA, INC.

Anti-HCV Seroconversion Panel (PHV907)

HCV Genotype 1A

Panel Member	Blood Date	Day No.	ABBOTT HCV 3.0 S/C/O	ORTHO HCV 3.0 S/C/O	Combo data Eq/07 ng/ml S/N	Ortho date Conjugate 2 ng/ml S/N	Abbott AB-Dialy Test S/C/O (17)	Roche Amplicon RNA copies/ml
PHV907-1		0	0.1	0.0	12.3	14.4	25.68	3 X 10 ⁶
PHV907-2		4	0.1	0.0	6.0	12.9	20.41	2 X 10 ⁶
PHV907-3		7	0.1	0.0	5.8	8.5	17.88	1 X 10 ⁶
PHV907-4		13	0.2	0.1	6.0	9.2	15.98	1 X 10 ⁶
PHV907-5		18	0.8	0.5	5.2	6.7	6.88	1 X 10 ⁶
PHV907-6		21	1.4	1.0	9.8	8.0	7.90	1 X 10 ⁶
PHV907-7		184	>5.0	>5.0	18.0	6.0	0.70	nd

Data above demonstrates on seven member seroconversion panel, that HCV RNA and HCV Antigens can be detected from the first bleed date () through the sixth bleed date, but the seventh bleed date is negative for HCV antigen. The antibody tests Ortho 3.0 and Abbott 3.0 failed to detect antibodies in the first five bleed dates () through ()...

The combo test detected exposure to HCV for all seven bleed dates.

SIGNATURE _____

DATE _____

WITNESSED BY _____

DATE _____

PROJECT PRISM HCV Ag/Ab combo

EXP. OR CODE NO. HCV combo Assay Random Donor Population

Reagents: Same as exp # 68160017.

1023 OMBG SMALL POP 6 A N/A 09/18/00 11:00:17 L. JIANG
HCV Combo Assay Population

SubA	SubB	Mean	P/N	Cutoff (3nc)	S/CO	Cutoff (2.5nc)	S/CO	Cutoff (2.33nc)	S/CO
3737	3854	3795.6	15.30	744	6.12	620	6.12	677.84	6.57
2949	2765	2867	11.56		4.62		4.62		4.98
214	282	248			0.29		0.29		0.31
182					0.26		0.26		0.28
163					0.47		0.47		0.51
282					0.28		0.28		0.30
4					0.43		0.43		0.46
6					0.28		0.28		0.30
6					0.44		0.44		0.47
7					0.32		0.32		0.35
7					0.40		0.40		0.43
8					0.32		0.32		0.35
8					0.40		0.40		0.43
200					0.32		0.32		0.35
247					0.40		0.40		0.43
10					0.32		0.32		0.35
11					0.40		0.40		0.43
12					0.32		0.32		0.35
13					0.40		0.40		0.43
14					0.32		0.32		0.35
14					0.40		0.40		0.43
15					0.32		0.32		0.35
15					0.40		0.40		0.43
16					0.32		0.32		0.35
16					0.40		0.40		0.43
17					0.32		0.32		0.35
17					0.40		0.40		0.43
18					0.32		0.32		0.35
18					0.40		0.40		0.43
19					0.32		0.32		0.35
19					0.40		0.40		0.43
20					0.32		0.32		0.35
20					0.40		0.40		0.43
21					0.32		0.32		0.35
21					0.40		0.40		0.43
22					0.32		0.32		0.35
22					0.40		0.40		0.43
23					0.32		0.32		0.35
23					0.40		0.40		0.43
24					0.32		0.32		0.35
24					0.40		0.40		0.43
25					0.32		0.32		0.35
25					0.40		0.40		0.43
26					0.32		0.32		0.35
26					0.40		0.40		0.43

SIGNATURE [Signature]

DATE

WITNESSED BY

[Signature]

DATE